

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

In re BAYCOL PRODUCTS LITIGATION

MDL No. 1431
(MJD/SER)

This document relates to:

*United States of America ex rel. Laurie
Simpson v. Bayer Corp., et al.*

Case No. 08-5758

**DEFENDANTS' REPLY IN SUPPORT
OF MOTION TO DISMISS**

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INTRODUCTION

In her Second Amended Complaint, Relator Laurie Simpson attempted to cure the pleading and jurisdictional defects that caused this Court to dismiss her original complaint. *See United States ex rel. Simpson v. Bayer Healthcare*, No. 08-5758, slip op. at 34-35 (D. Minn. Sept. 30, 2010) (memorandum opinion and order) (Dkt. No. 50) (“Mem. Op.”) (Ex. 35). Her attempt fails. As Bayer demonstrated in its opening memorandum, Simpson has still failed to provide “particularized allegations as to at least representative claims” to support her False Claim Act (“FCA”) causes of action. *Id.* at 29.

In response to Bayer’s opening memorandum, Simpson largely repeats the same arguments that this Court already considered and rejected. She contends that her theory of liability in this case—that Bayer’s deceptive marketing scheme necessarily rendered all Baycol claims submitted to the government false—absolves her of the normal pleading requirements, such as providing detailed allegations of representative claims and pleading the *scienter* required by the FCA. As this Court has already held, Simpson is wrong. Following the Eighth Circuit’s decision in *United States ex rel. Joshi v. St. Luke’s Hospital, Inc.*, 441 F.3d 552, 558 (8th Cir. 2006), this Court concluded that Simpson’s theory does not diminish the normal pleading requirements. She still must provide “particularized allegations as to at least representative claims.” Mem. Op. 29. But she still “has not alleged any facts” in the complaint “which would identify a single false claim submitted to the government, such as submission dates, identities of persons or entities submitting false claims or even facts as to standard billing practices.” *Id.* at 30-31.

Recognizing the deficiency of her actual pleadings, Simpson has attempted belatedly to add to them by submitting an exhibit to her opposition brief that purportedly contains 30,000 Medicaid claims. Simpson's last-ditch effort to bolster her complaint should not be countenanced by the Court. On a motion to dismiss, the Court generally does "not consider evidence outside the complaint." *Penn v. Iowa State Bd. of Regents*, 999 F.2d 305, 307 (8th Cir. 1993). Moreover, the hardly-legible document does not indicate what the data represent. And Simpson has done nothing to indicate what aspects of these particular state-level claims were submitted for payment to the *federal* government.

Simpson's remaining arguments are equally meritless. *First*, she does not respond to Bayer's argument that her allegations about the knowledge of senior management do not satisfy the *scienter* requirement of the FCA because they fail to identify a single person who knew that a particular false claim was being filed. And, as Bayer explained, the D.C. Circuit has recently rejected Simpson's "'collective knowledge'" theory of corporate *scienter* as incompatible with the FCA's "language, structure and purposes." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010).

Second, Simpson cannot salvage her entirely new allegations regarding PacifiCare studies and DoD contracts. Bayer demonstrated that the Court lacks jurisdiction over these new allegations because Simpson is not an original source of them, and, in all events, they are time barred. Simpson contends only that she is an original source of the allegations because they simply "add detail" to her original complaint. But Simpson wholly fails to confront Bayer's argument that these new allegations present entirely new and distinct theories of fraud and, thus, cannot be considered mere "additional detail."

Moreover, because Simpson is alleging entirely new theories of fraud, her allegations do not relate back to the conduct, transaction, or occurrence set forth in her original complaint and, therefore, are barred by the statute of limitations. Further, Simpson does not have leave to replead allegations that this Court already has dismissed for lack of jurisdiction. The Court expressly denied such leave. Mem. Op. 35 (permitting amendment of complaint only “as to those allegations over which the Court has subject matter jurisdiction, as discussed” earlier in the opinion).

Third, Simpson has no response to Bayer’s argument that her Anti-Kickback Statute-based FCA claim fails to state a claim and is factually deficient. Allegations that Bayer certified compliance with a statute or regulation as a condition to government payment do not call for an impermissible “legal conclusion” but rather form an element of her claim that must be pled and proven. *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005).

Finally, Simpson does not respond meaningfully to the fact that her state FCA claims must be dismissed. She agrees that, at a minimum, these state laws should be interpreted consistently with federal law. But she has no response to the fact that many of these states have more stringent jurisdictional provisions and statutes of limitations, requiring outright dismissal of these claims.

For all these reasons, Simpson’s Second Amended Complaint should be dismissed.

ARGUMENT

I. SIMPSON CANNOT SHOW THAT HER CLAIMS ARE PLED WITH SPECIFICITY OR SUPPORTED BY LAW.

A. Simpson Cannot Justify Her Failure To Provide Particularized Allegations Of Representative False Claims.

As Bayer demonstrated in its opening memorandum, Simpson's Second Amended Complaint must be dismissed because she has failed to plead her FCA claims with the particularity required by Rule 9(b). Mem. of Law in Support of Defendants' Mot. to Dismiss ("MTD") at 8-12 (Dkt. No. 56). Specifically, as in her First Amended Complaint, Simpson *still* has not pled a single, identifiable false claim or "alleged any facts which would identify a single false claim submitted to the government, such as submission dates, identities of persons or entities submitting false claims or even facts as to standard billing practices." Mem. Op. 30-31. Bayer explained (1) that Simpson's allegations of aggregate "government" spending on Baycol, Second Amended Complaint ("SAC") ¶¶ 243-254 & Ex. C (Dkt. No. 52), are insufficient under Rule 9(b) because she "has not alleged any facts that would identify a single false claim submitted to the government," MTD 11 (quoting Mem. Op. 30), and because even that aggregated data is insufficiently vague, *id.* at 10-11 (citing SAC ¶ 243); and (2) that Simpson's allegations regarding adverse event reports, SAC ¶¶ 237-242, are insufficient because they all occurred outside the applicable statute of limitations period, and because Simpson fails to allege any details regarding the actual submission of a claim associated with these adverse events. MTD 10.

Rather than meeting these arguments, Simpson tries to justify the deficient "aggregate data" and "adverse event report" allegations in her complaint by referencing

her “deceptive marketing” theory. Mem. of Law in Opposition to Defendants’ Mot. to Dismiss (“Opp.”) at 9 (Dkt. No. 60); *see also id.* at 11, 13-15. She claims that the details of any false claims are unnecessary because “Bayer’s deceptive marketing scheme rendered each Baycol claim to be false,” making the mere allegation “that claims were made at all” sufficient. *Id.* at 11. This Court has already rejected Simpson’s argument based on controlling Eighth Circuit precedent.

In dismissing Simpson’s First Amended Complaint, which presented the same theory, this Court compared Simpson’s claims to those in *Joshi*, 441 F.3d at 556, in which the “relator argued it was not necessary to include specific allegations as to the claims themselves, where ‘all’ claims for anesthesia services were fraudulently submitted.” Mem. Op. 27. This Court rejected Simpson’s deceptive marketing theory—along with her “conclusory and generalized allegations,” *id.*—requiring instead that Simpson must present “particularized allegations as to at least representative claims” even “where the focus of the fraudulent conduct is in the marketing of a drug.” *Id.* at 28-29. The Court’s holding closely tracked *Joshi*, in which the Eighth Circuit made clear that “to satisfy Rule 9(b)’s particularity requirement and to enable [the defendants] to respond specifically to [the] allegations, [a relator] must provide *some* representative examples of their alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors.” 441 F.3d at 557 (emphasis in original).

Without acknowledging this Court’s prior holding in this case, Simpson nevertheless attempts (at 13-15) to distinguish *Joshi* by arguing “that *Joshi* is limited to the unique set of facts at issue in that case.” Mem. Op. 30. But this Court has already concluded that “there is nothing in the *Joshi* opinion which so limits the decision.” *Id.*

Moreover, many of the decisions this Court cited in dismissing Simpson's First Amended Complaint required representative examples and particularized allegations even when the relator alleged a wide-ranging fraud involving *no claim-specific deception*. See *id.* at 28-30.¹

In addition to ignoring this Court's holding, Simpson ignores post-*Joshi* case law, which reaffirms the need for representative examples—including allegations concerning the time, place, and content of the fraudulent acts and identity of the actors—even when the complaint “alleges a systematic practice of submitting fraudulent claims.” *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009). The Eighth Circuit's decision in *Roop*—which required allegations of actual claims when, as here, the relator alleged that the defendant's nondisclosure of a product defect affected all claims, *id.* at 820-21—squarely forecloses Simpson's argument.²

Thus, Simpson errs in asserting (at 15) that her complaint is sufficient because she has “provided very detailed, nonconclusory allegations” regarding the underlying fraud.

¹ See, e.g., *United States ex rel. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th Cir. 2008) (applying “the requirement that Relator identify with particularity a claim for payment” where the relator proceeded on a fraudulent inducement theory alleged to taint all claims under the affected contracts); *United States ex rel. Hopper v. Solvay Pharms., Inc.*, 590 F. Supp. 2d 1352, 1361-1362 (M.D. Fla. 2008), *aff'd*, 588 F.3d 1318 (11th Cir. 2009), *cert. denied*, 130 S. Ct. 3465 (2010).

² Simpson also argues that *Joshi* is “inapplicable” to the point raised by Bayer that a relator, to survive Rule 9(b), must “plead some representative examples *within the statute of limitations*.” *Joshi*, 441 F.3d at 560 (emphasis added). According to Simpson, *Joshi* is inapplicable because the time-barred allegations there contained no details of the claims themselves and were unconnected to a pattern of conduct. Opp. 12-13. But, like the allegations in *Joshi*, Simpson's “adverse event” allegations contain no details regarding the actual submission of claims. And an alleged adverse event from outside the limitations period is no more indicative of claims “within the statute of limitations” than were the allegations at issue in *Joshi*. Tellingly, Simpson does not identify a single case allowing a relator to proceed on the basis of time-barred claims.

It is well established that “Rule 9(b) ‘does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply ... that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.’” *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)) (alteration in original). After all, “[t]he FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment.” *Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998) (internal quotation marks omitted).³

Indeed, the only affirmative support Simpson cites for her “deceptive marketing” theory consists of two out-of-circuit district court decisions. Opp. 14 (citing *United States ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp. 2d 522, 527 (M.D. Pa. 2008); *United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, No. 1:03-CV-00167, 2008 WL 5282139, at *13 (S.D. Ohio Dec. 18, 2008)). These decisions not only contradict controlling Eighth Circuit precedent, but they contradict the controlling precedent within their respective circuits. See, e.g., *United States ex rel. Quinn v.*

³ If anything, the nature of the underlying fraudulent activity confirms the need for allegations regarding individual claims. For instance, to state a claim under 31 U.S.C. § 3729(a)(1) based on false claims submitted by healthcare providers, Simpson must allege that Bayer “caused” such claims “to be presented.” But due to the many factors that influence individual doctors’ prescribing decisions, it is well-established that when the underlying fraud involves the marketing of a drug, causation must be established through an individualized showing, not aggregate data. E.g. *In re Neurontin Mktg. & Sales Practices Litig.*, 677 F. Supp. 2d 479, 494 (D. Mass. 2010) (“[T]rial courts have almost uniformly held that in a misrepresentation action involving fraudulent marketing of direct claims to doctors, a plaintiff ... must prove through *individualized evidence* that the misrepresentation caused specific physicians, [payers], or consumers to rely on the fraud, and cannot rely on aggregate or statistical proof.”) (emphasis added).

Omnicare Inc., 382 F.3d 432, 434 (3d Cir. 2004) (relator’s “failure to present evidence of the actual submission of a single false claim to Medicaid” was “fatal” to his FCA action); *United States ex rel. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th Cir. 2008) (applying “the requirement that Relator identify with particularity a claim for payment” where the relator proceeded on a fraudulent inducement theory alleged to taint all claims under the affected contracts).

Simpson’s remaining arguments to evade *Joshi* also fail:

- She argues that “‘nothing requires [a relator] to state *every* factual detail concerning *every* alleged fraudulent claim submitted’” because the purpose of Rule 9(b) is simply to provide notice. Opp. 15 (quoting *United States ex rel. Murphy v. Baptist Medcare, Inc.*, No. 4:02-CV-440, 2006 WL 3147440, at *2 (E.D. Ark. Nov. 1, 2006)) (first alteration in original; emphasis added). But “notice is not the only reason for the requirement of Rule 9(b).” *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007).⁴ And even if Simpson were correct that not *every* claim must be presented in the pleadings, it would not excuse her failure to allege *any* claims in her Complaint.
- Simpson also claims incorrectly that she is entitled to a “‘more flexible [FCA pleading] standard’” because the supposedly false claims were submitted by third parties and therefore unavailable to her—a standard she readily admits the Eighth Circuit has not adopted. Opp. 16 & n.3. But in *Joshi*, the Eighth Circuit, in fact, *considered and rejected* the argument that a court may “relax Rule 9(b)’s pleading requirements” for FCA complaints because the information is inaccessible to the relator. 441 F.3d at 559. It explained that such a relaxed standard “may needlessly harm a defendant’s goodwill and reputation by bringing a suit that is ... missing some of its core underpinnings.” *Id.* (alterations and internal quotation marks omitted). Indeed, this Court followed this very holding in stating that “lack of access

⁴ For example, the particularity requirement is also based on the recognition that “[i]t is a serious matter to accuse a person or company of committing fraud, and the mere accusation often causes harm.” *Pfizer, Inc.*, 507 F.3d at 733 (citing 5A Wright & Miller, *Federal Practice and Procedure* § 1296 (3d ed. 2004)). In addition, Rule 9(b) “discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement.” *Id.*

to details does not excuse Relator from meeting the particularity requirements of Rule 9(b).” Mem. Op. 30.⁵

Finally, in a desperate attempt to salvage her complaint, Simpson essentially abandons the allegations in the complaint by submitting an exhibit to her opposition brief that supposedly contains 30,000 Medicaid claims. *See* Declaration of Robert W. Sadowski (“Sadowski Decl.”) ¶ 3 & Ex. 1 (Dkt. No. 62). She claims that the Court should ignore the dispute about the inadequacy of the allegations in her actual complaint (as “moot”) and focus solely on this new exhibit. Opp. 11. This maneuver fails.

This exhibit should not be considered in ruling on Bayer’s motion to dismiss. The well-established rule is that “[w]hen considering a motion to dismiss for failure to state a claim, a court must accept the factual allegations in the complaint as true, and *may not consider evidence outside the complaint.*” *Penn*, 999 F.2d at 307 (emphasis added); *see also Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999); *Noble Sys. Corp. v. Alorica Cent., LLC*, 543 F.3d 978, 982 (8th Cir. 2008).⁶ The Court ought to reject Simpson’s procedurally improper attempt to salvage her deficient complaint.

⁵ Even if a relaxed standard did apply, it would not excuse Simpson’s particular pleading deficiencies. Even under the “more flexible standard,” a relator still must allege significant detail regarding the actual submission of claims. For example, in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009), the relator was allowed to proceed without identifying specific claims in her complaint, but only because she provided considerable detail regarding the submission of claims, including the identities of each of the health care providers alleged to have submitted false claims, along with individualized details regarding each of the providers at issue. *Id.* at 30. In contrast, Simpson’s complaint does not even identify anyone who submitted false claims, let alone what billing practices or methods were followed.

⁶ There are certain limited exceptions to this general rule that permit a court to consider “some public records” or “materials that are ‘necessarily embraced by the pleadings,’” such as exhibits referenced in the complaint itself. *Noble Sys.*, 543 F.3d at 982 (quoting *Porous Media*, 186 F.3d at 1079). But Simpson provides no basis to conclude that this

Even if this exhibit could be considered, it would not cure the complaint's deficiencies. First, Simpson's reliance on this document is just another variation on her failed assertion that she does not need to show fraud as to individual claims. Even if she were correct that this document shows individual claims, she still has provided no claim-specific allegations, such as what allegedly fraudulent acts (and by whom) caused the individual providers involved in these transactions to submit false claims to the federal government. *Cf. In re Neurontin Mktg. & Sales Practices Litig.*, 677 F. Supp. 2d at 494. Second, Simpson has not even provided sufficient information to enable either Bayer or this Court to assess whether the spreadsheet actually lists any claims for payment from the federal government. Simpson's attorney asserts that it "is a spreadsheet of Medicaid claim data," Sadowski Decl. ¶ 3, but it is impossible to decipher what exactly the spreadsheet represents, and Simpson's attorney provides no other information about it. A dollar figure appears on one side of each page of the document, but there is no indication of what this represents—whether these are amounts submitted or paid, and most importantly, whether these particular state-level claims were submitted for payment to the *federal* government. Whatever the document may say about claims in Florida, it provides

exhibit falls within such an exception to the general rule. For example, she provides no grounds to conclude that this is a publicly available document, declaring only that it is a "spreadsheet" with "claim data from the Florida Medicaid Agency for Healthcare Administration." Sadowski Decl. ¶ 3. Indeed, there is no indication whatsoever that either the information or the document is available to the public. Moreover, Simpson provides no information regarding the authenticity or reliability of this barely legible document. She does not state who created it, for what purpose, how it was obtained, or any other pertinent information. Nor is the document embraced by her pleadings; not once in her complaint does she refer to this document, much less to the Florida Medicaid Agency for Healthcare Administration.

no cognizable information about Simpson's federal FCA claims.⁷ Ultimately, Simpson's desperate attempt to save her complaint does nothing more than confirm the deficiency of her actual pleadings.

B. Simpson Cannot Cure Her Failure To Plead The Required *Scienter* Under The FCA.

As an alternative basis for dismissal of Simpson's Second Amended Complaint, Bayer demonstrated that Simpson has failed to plead the *scienter* necessary under the FCA. See MTD 12-15; see also *United States v. Taber Extrusions, LP*, 341 F.3d 843, 845 (8th Cir. 2003). To plead the *scienter* of a corporate defendant, Simpson cannot rely on a "collective knowledge" theory but must allege that a particular employee knew *both* that a claim was being submitted *and* that it was false, which she fails to do. MTD 13-14. Simpson improperly relies on the "collective knowledge" of Bayer, erroneously extrapolating that the elements of the FCA have been met because certain members of Bayer's management were aware that the government paid for Baycol prescriptions. *Id.*

Simpson's first response is to disingenuously claim that, in the memorandum opinion dismissing her First Amended Complaint, this Court already rejected Bayer's *scienter* argument. Opp. 16-17. Simpson does not and cannot point to any holding from the Court. She instead cites the Court's summary of the parties' arguments and then asserts that "the Court correctly did not hold that Relator pled *scienter* insufficiently." *Id.* (citing Mem. Op. 4). But the Court did not issue a holding regarding *scienter* because it did not reach the issue at all; Simpson's failure to plead her FCA claims with specificity

⁷ As Bayer demonstrated, the statute of limitations bars all of Simpson's Florida-based FCA claims because she filed outside the applicable 5-year limitations period. MTD 38.

independently required dismissal. Mem. Op. 34-35. Because this Court did not issue any holding on *scienter*, Simpson's attempt to foreclose Bayer's arguments fails.

Simpson makes three additional arguments in support of her "collective knowledge" theory, none of which withstands examination. *First*, Simpson argues that her allegations are sufficient in light of her theory that "Bayer's deceptive marketing rendered each of the claims presented to the Government false." Opp. 18. In other words, because she alleges (incorrectly) that senior management had knowledge of "deceptive marketing," they should be imputed with knowledge that this would "result in the submission of false claims to the Government." *Id.* But as discussed above, *see supra* pp. 5-7, Simpson cannot state a claim under the FCA—and cannot establish *scienter*—merely by arguing that "'every' claim was fraudulent," that some claims were submitted to the government, and, therefore, that the defendant must have known about fraudulent claims. *Cf. Joshi*, 441 F.3d at 557 (requiring allegation of particular claims even though relator alleged that "'every' claim was fraudulent."). Indeed, Simpson has no response to the argument in Bayer's opening memorandum (or the supporting case law) that a relator cannot extrapolate that the elements of an FCA claim have been satisfied because all claims submitted to the government are alleged to have been fraudulent. *See* MTD 14.

Second, Simpson has no adequate response to Bayer's argument that her bare allegations about senior management's general knowledge of government sales are too "conclusory" to satisfy the Federal Rules. *See id.* Simpson claims that *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), "is inapposite" because that case did not involve FCA claims. Opp. 18. Her claim is baseless. The Supreme Court has made clear that, in all cases

governed by the Federal Rules of Civil Procedure, the Rules require more than “labels and conclusions,” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), or “conclusory statements” devoid of “factual context,” *Ashcroft*, 129 S. Ct. at 1954. Nor are her “detailed allegations here about Bayer’s knowledge” sufficient. Opp. 18. Detail about “Bayer’s [collective] knowledge”—as a corporate entity—is insufficient to maintain an FCA claim, and Simpson has failed to provide sufficient allegations about the *individual knowledge* of any Bayer employee to satisfy the *scienter* requirement of the FCA. MTD 13-14.

Finally, Simpson tries to justify her use of the “collective knowledge” theory by calling the requirement that she identify a person within Bayer that had knowledge of both fraudulent marketing and the submission of a false claim “ludicrous” and without “authority in support.” Opp. 19. But this requirement is well established. MTD 12-13. Recent decisions from the courts of appeals reject any attempt to piece together the knowledge held by disparate corporate officials in an effort to establish the *scienter* of a corporate defendant under the FCA. *See Sci. Applications Int’l Corp.*, 626 F.3d at 1277; *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 & n.9 (4th Cir. 2003); *see also United States v. United Techs. Corp.*, 51 F. Supp. 2d 167, 197-99 (D. Conn. 1999). Cobbling together knowledge from different employees within a company in order to establish a collective corporate knowledge is incompatible with the “balance” Congress struck in the FCA between deterring fraud and punishing mere negligence. *Sci. Applications Int’l Corp.*, 626 F.3d at 1274. Attempting to establish *scienter* in this way “effectively imposes liability, complete with treble damages and

substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the [FCA]’s language, structure and purposes.” *Id.*⁸

Simpson attacks the court of appeals decisions relied upon by Bayer as “inapplicable” because they did not involve “motions to dismiss” or the “requirements for pleading.” Opp. 19. This is a red herring. These cases firmly establish the necessary standard for any FCA claim, whether at the pleadings stage or after trial. Simpson’s allegations fail to state a claim because they fail to satisfy that standard for an FCA claim.

Simpson also tries to distinguish these cases by contending that “the ‘collective knowledge’ doctrine would allow a plaintiff to prove *scienter* by piecing together scraps of ‘innocent’ knowledge” and arguing that she has alleged “Bayer management was anything but ‘innocent.’” Opp. 19-20. Simpson misreads the courts’ discussion of “innocent knowledge.” The courts’ statement about “innocent knowledge” refers to the concept that no “particular ... employee” had the knowledge requisite to violate the FCA. *Sci. Applications Int’l Corp.*, 626 F.3d at 1274. Because no employee had the necessary knowledge, a plaintiff could not establish the company’s *scienter* by piecing together the knowledge of several employees who each individually fall short of the standard. *Id.* To be sure, Simpson has done her best to malign individuals within Bayer, not to mention

⁸ Indeed, consistent with these court of appeals decisions, the Supreme Court in a different context recently observed the basic principle of agency law that “the malicious mental state of one agent cannot generally be combined with the harmful action of another agent to hold the principal liable for a tort that requires both.” *Staub v. Proctor Hosp.*, 131 S. Ct. 1186, 1191 (2011).

Bayer itself, but she has fallen far short of alleging that any individual has the knowledge of all the elements necessary to establish *scienter*. See MTD 13-15.⁹

II. SIMPSON CANNOT SALVAGE HER BARRED CLINICAL TRIAL, PACIFICARE, AND DoD ALLEGATIONS.

In its opening memorandum, Bayer demonstrated that the Court should dismiss Simpson's new allegations regarding clinical trials, supposed complicity in fraudulent PacifiCare studies, and alleged fraud in obtaining and maintaining contracts with DoD and other governmental entities. MTD 16-31. These new allegations are beyond the Court's jurisdiction, because Simpson is not an original source of them, or barred by the statute of limitations, and the claims based on these allegations, therefore, should be dismissed.

Simpson asserts—without authority—that it is “procedurally improper” for Bayer to seek dismissal in this way because Bayer's arguments relate to particular allegations, not entire causes of action. Opp. 26. But in ruling on Bayer's prior motion to dismiss, this Court did precisely that—it dismissed certain allegations and related claims, but not others, because Simpson was not an original source, or because the statute of limitations

⁹ Simpson raises a complete non-sequitur in contending that neither *Scientific Applications* nor *Harrison* “contradicts the well-established law that ... a company's knowledge can be imputed from its employees' actions.” Opp. 20. The issue is not whether an individual employee's actions can be imputed to the employer. It is that Simpson has failed to demonstrate that any particular employee had the knowledge necessary to establish *scienter* under the FCA. The courts' rejection of the “collective knowledge” theory merely recognizes that a particular employee must have knowledge of all the necessary elements for *scienter* to be imputed to Bayer. Cobbling together knowledge from multiple employees will not do.

barred aspects of her claims. *See* Mem. Op. 24, 34-35.¹⁰ Like the allegations in Simpson's First Amended Complaint that this Court specifically dismissed, Simpson's new clinical trial, PacifiCare, and DoD allegations should be dismissed. Further, Simpson's other responses to Bayer's jurisdictional and statute-of-limitations arguments are equally meritless.

A. Simpson Cannot Demonstrate That This Court Has Subject-Matter Jurisdiction Over Her New Allegations.

Bayer showed that Simpson's allegations regarding clinical trials, PacifiCare, and DoD should be dismissed for lack of jurisdiction because Simpson has failed to establish that she is an original source of these publicly disclosed allegations. MTD 16-26. Because these allegations are based upon public disclosures, the Court could only have jurisdiction if Simpson was "an original source of the information." 31 U.S.C. § 3730(e)(4)(A). But Simpson is not an "original source" because she does not have "direct and independent knowledge of the information on which the allegations are based," nor has she "voluntarily provided the information to the Government." *Id.* § 3730(e)(4)(B); *see* MTD 16-26.

As an initial matter, Simpson was not granted leave to replead her allegations regarding clinical trials and certain kickbacks. As Bayer explained in its opening memorandum (at 23), this Court previously dismissed these allegations for lack of jurisdiction and granted Simpson leave to amend her complaint only "as to those

¹⁰ In all events, Simpson mischaracterizes Bayer's motion. Bayer has moved to dismiss Simpson's *entire* complaint on a number of grounds, arguing in its opening memorandum (at 21 & n.14) that Simpson is not an original source of *any* of her allegations. Because the allegations Simpson repeats have already been briefed and considered by this Court, Bayer focused its briefing on the allegations Simpson introduced for the first time in her new complaint.

allegations over which the Court has subject matter jurisdiction, as discussed” earlier in the opinion, Mem. Op. 35. *Compare also Amended Complaint* (“AC”) ¶¶ 83-85, 87, 130 (Dkt. No. 6), *with* SAC ¶¶ 175-177, 179, 230-236. There is no dispute that Simpson’s ability to amend her complaint is limited by the conditions this Court placed upon her leave to amend. *See* Fed. R. Civ. P. 15(a)(2). Simpson’s claim (at 28) that she may replead these allegations by adding additional details, because those details might affect the jurisdictional inquiry, would render the Court’s limitation meaningless. Moreover, the Court did not dismiss her allegations based on an insufficiency of her pleadings; it made a *factual* determination in which it properly “consider[ed] evidence *outside* of the pleadings.” Mem. Op. 5-7 (emphasis added); *see also* MTD 22 n.15.

Simpson has failed to establish that she is an original source of her allegations regarding the DoD contract and PacifiCare studies. Bayer demonstrated in its opening memorandum (at 24-25) that Simpson is not an original source of these new allegations. Simpson attempts to avoid her affirmative burden of establishing that she is an original source (MTD 22-25) by contending that she need not make this demonstration, because her new allegations “are simply additional details ... and thus are perfectly proper.” Opp. 27. But Simpson is now alleging fraudulent acts that are separate and distinct from those alleged in her previous complaint—fraudulent inducement of the DoD contract and fraudulent use and design of the PacifiCare studies. *See* MTD 29-30; *see also* SAC ¶¶ 59-124, 125-138; *infra* pp. 19-22. Simpson never responds to Bayer’s specific points other than to make the broad assertion that she is adding details. Simpson cannot establish that she is an original source of the allegations regarding one supposed fraud by

arguing that she is an original source of the allegations regarding *other* different frauds. *Cf.* Mem. Op. 24 (analyzing jurisdiction separately for different allegations of fraud).

Indeed, as to all of Simpson's new allegations—including the new details regarding the allegations this Court already dismissed—Simpson's only substantive response is to note this Court's holding that Simpson's "'2003 deposition testimony in no way rebuts her assertion that she is an original source of the information underlying her claims.'" Opp. 27 (quoting Mem. Op. 21). But Simpson mischaracterizes this Court's holding. Contrary to Simpson's suggestion, this Court did *not* issue a blanket holding that her 2003 deposition testimony confirms her position as an original source. Rather, the language Simpson quotes related only to particular allegations; as to other allegations, this Court specifically held that the same testimony *does* rebut her assertion that she is an original source. Mem. Op. 24. Indeed, this testimony proved that she is not an original source of the clinical trial allegations at issue here. *Id.* ("Relator specifically testified that she was not involved in the structure of clinical trials.").

Finally, Simpson has no adequate response to Bayer's argument that she fails to qualify as an original source of her new allegations because she has not "voluntarily provided the information [on which the allegations are based] to the Government." 31 U.S.C. § 3730(e)(4)(B); *see* MTD 26. Simpson claims (at 27) that she has met this requirement by declaring that the information she disclosed to the Federal Government in early 2005 "included information relating to the PacifiCare studies and to the Department of Defense Contract." Declaration of Laurie Simpson ("Simpson Decl.") ¶ 2 (Dkt. No. 61). This carefully worded statement does not specify whether this information "relating to" PacifiCare and the DoD contract is the same information on which her new

allegations are based. And it certainly does not establish that Simpson provided the Government with “written disclosure of substantially all material evidence and information [she] possesses” with respect to her new allegations. 31 U.S.C. § 3730(b)(2). Simpson also suggests, without authority, that her initial disclosure satisfied the FCA’s disclosure requirement because her new allegations “merely supplement and support” her “core allegations.” Opp. 27. But, as explained, these allegations present new theories of fraud, and not just additional details.¹¹

B. The FCA Statute of Limitations Bars Simpson’s New PacifiCare And DoD Allegations.

Bayer demonstrated that several of Simpson’s new allegations must also be dismissed because they are barred by the FCA’s statute of limitations. Simpson’s DoD and PacifiCare allegations do not relate back to the filing of her original complaint under Federal Rule 15(c)(1)(B) because they are not of the same “time and type” as the allegations in her original complaint. MTD 28-30. And the new theories of fraud in Simpson’s new PacifiCare and DoD allegations bear no relationship to the passing references made to PacifiCare and DoD in her original complaint and so lack a common core of operative facts. *Id.* at 29-30. Separately, Simpson’s DoD allegations are in all events barred by the statute of limitations because they seek relief for conduct that occurred outside the limitations period. FCA claims based on fraudulent inducement of a contract—such as her new DoD allegations—run from the time of the fraudulent

¹¹ The declaration of Simpson’s lawyer that his law firm “provided the Federal and applicable State Governments with a copy of the Second Amended Complaint,” Sadowski Decl. ¶ 2, is likewise deficient. The declaration refers only to the complaint itself, not the “evidence and information” that Simpson was also required to disclose. *See* 31 U.S.C. § 3730(b)(2).

inducement, which Simpson alleges took place before October 5, 2000. *Id.* at 30-31. Simpson has no meritorious response to any of these points.

Simpson responds to Bayer's first point—that her new allegations do not relate back to her original complaint—by proclaiming it “blatantly false.” Opp. 28. Yet she entirely fails to respond to the authority Bayer cited, much less the specific arguments Bayer made. Beyond asserting that her new allegations regarding PacifiCare and DoD are “new details” that “merely support” her “core allegations,” Opp. 29, Simpson does not address Bayer's actual argument. To satisfy Rule 15 “[t]he *allegations* [in the amended pleading] ... ‘must be of the same “time and type” as those in the original motion,’” such that “the facts [as originally] alleged ... put the opposing party on notice of the factual basis for the claim.” *Dodd v. United States*, 614 F.3d 512, 515-16 (8th Cir. 2010) (emphasis added); *see also* 6A Arthur R. Miller et al., *Federal Practice and Procedure* § 1497, at 87-89 (2010).

Simpson's new allegations fail this standard because the 79 new paragraphs allege distinct fraudulent acts nowhere averted to in the original complaint. *See* SAC ¶¶ 59-138. The original complaint made only cursory reference to the PacifiCare studies and DoD contract: Simpson alleged only that (1) a PacifiCare study showed Baycol's deficient performance, AC ¶ 101; (2) Bayer provided free samples to PacifiCare, *id.* ¶ 130(f); and (3) Bayer used “aggressive tactics” when negotiating a contract with DoD, including “entic[ing]” DoD “with deep discounts on Baycol,” *id.* ¶¶ 43-46. The Second Amended Complaint, however, adds entirely new and distinct theories of fraud, namely that Bayer fraudulently engineered a false PacifiCare study, SAC ¶¶ 125-138, and fraudulently secured the DoD contract, *id.* ¶¶ 59-124. Simpson does not challenge the authority on

which Bayer relies. Nor does she respond to Bayer's specific points. Simpson's new allegations (*id.* ¶¶ 59-138) do not relate back to the original complaint and are, therefore, barred by the statute of limitations.

Simpson also argues that because the Court already held that the statute of limitations bars her claims that are based on false claims submitted before October 5, 2000, *see* Mem. Op. 31, she is at liberty to allege anything related to claims submitted after this date. Opp. 28-29. But the Court merely identified the relevant limitations period; Simpson is still bound by Rule 15's requirement that amended pleadings must relate back to the conduct, transaction, or occurrence set forth in the original pleading.

Similarly meritless is Simpson's argument that her new allegations based on the DoD contract are not barred by the statute of limitations because "Baycol claims were submitted to the Government [through] the DoD contract after October 5, 2000." Opp. 28. Bayer demonstrated that when, as here, an FCA claim is based on the alleged fraudulent inducement of a contract, the statute of limitations runs from the time of the fraudulent inducement, not from the later date on which the resulting claims were submitted. MTD 30-31 & n.25 (citing *United States ex rel. Frascella v. Oracle Corp.*, __ F. Supp. 2d __, 2010 WL 4623793, at *2, *6-10 (E.D. Va. Nov. 2, 2010); *United States ex rel. Dugan v. ADT Sec. Servs.*, 2009 WL 3232080, at *4 (D. Md. Sept. 29, 2009); *United States ex rel. Vosika v. Starkey Labs., Inc.*, 2004 WL 2065127, at *3 (D. Minn. Sept. 8, 2004)). Despite her bare protests, Simpson never grapples with the authority cited by Bayer. Accordingly, regardless of whether Simpson's DoD allegations relate back to her original complaint, these allegations—which center on alleged fraudulent inducement of government contracts, *see* SAC ¶¶ 60-72, 81-92, 105-124—are time-

barred because they seek relief for conduct that occurred before October 5, 2000. *See* 31 U.S.C. § 3731(b)(1).¹²

III. SIMPSON CANNOT SALVAGE HER LEGALLY AND FACTUALLY DEFICIENT ANTI-KICKBACK FCA CLAIM.

In its opening memorandum, Bayer showed that dismissal of Simpson's Anti-Kickback-based FCA claim is warranted. MTD 31-36. Bayer explained that Simpson's attempt to resurrect her dismissed claims under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7, by repleading the same allegations as a violation of the FCA itself under a "false certification" theory, failed for multiple reasons. *See* SAC ¶¶ 207-236; *see also* Opp. 29-30. First, even assuming an FCA claim may be based on this theory, Simpson's allegations here do not support such a claim because she fails to allege that Bayer "[fraudulently] *certifie[d]* compliance with a statute or regulation *as a condition to governmental payment.*" *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (emphases added); *see also* MTD 32-34. Second, Simpson has failed to plead the appropriate *scienter* to satisfy the FCA as to her Anti-Kickback Statute-based claim. Finally, Simpson has failed to provide the necessary particularity to satisfy Rule 9(b). MTD 33-35. Simpson's responses are meritless.

First, Simpson asserts that she does not have to allege that a provider made a false certification as a *condition of payment* because that is an impermissible "legal

¹² Bayer also demonstrated in its opening memorandum that Simpson's new DoD allegations should be dismissed because the government entered into a broadly worded settlement that released Bayer of "all claims ... known or unknown, arising under or related to" the DoD contract. MTD 26-27. Simpson responds with a tangled series of arguments that ultimately fail to rehabilitate her claims. Opp. 20-25. This Court need not enter the thicket. As explained above, the relevant allegations are barred both jurisdictionally and by the statute of limitations, and those grounds serve as sufficient bases for dismissal.

conclusion.” Opp. 29-30. She is wrong. A fundamental element of an FCA claim under a “false certification” theory is that the certification “be a condition of or prerequisite to government payment,” *Gross*, 415 F.3d at 604, because “[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA,” *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996). Where a plaintiff fails to allege this element of her claim, she fails to state a claim, and dismissal under Rule 12(b)(6) is proper. *See Gross*, 415 F.3d at 605; *accord Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 793 (4th Cir. 1999) (“[The FCA] claim fails on the pleadings because [the relator] has never asserted that such implied certifications were in any way related to, let alone prerequisites for, receiving continued funding.”). Moreover, this allegation is necessary for a relator properly to allege that any false statement in the certification was *material* to the Government’s decision to pay, which is a separate element of an FCA claim. *See, e.g., Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665 (2008)¹³; *United States ex rel. Costner v. United States*, 317 F.3d 883, 886-87 (8th Cir. 2003).¹⁴

Contrary to Simpson’s assertions, not every violation of the Anti-Kickback Statute will support liability under a “false certification” theory. For example, in *United States*

¹³ *See* MTD 7 n.6 (noting that Congress amended the FCA in 2009 but those amendments do not apply retroactively).

¹⁴ Bafflingly, Simpson asserts that Bayer “does not dispute” either that “a certification was indeed a precondition for Government payment” or that “a violation of a statute that a defendant certified to comply with as a precondition to payment will necessarily result in [FCA] liability.” Opp. 29. As Bayer demonstrated, Simpson wholly failed to make the necessary allegation (and supporting context) that a certification was a precondition for Government payment. MTD 32-33. Thus, there is no allegation to dispute. Moreover, Bayer made abundantly clear that not all violations of rules or statutes will necessarily result in FCA liability. *Id.* at 32.

ex rel. Thomas v. Bailey, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008), the court held that the doctor allegedly receiving kickbacks had too indirect a relationship with the hospital submitting the claims to support “false certification” liability. *Id.* at *9. Likewise, in *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28 (D.D.C. 2003), the court dismissed the relator’s Anti-Kickback Statute-based FCA claims because the complaint failed to connect the alleged kickbacks to Medicare claims or the referring physicians and the facilities. *Id.* at 35. A relator simply cannot proceed under a “false certification” theory without alleging the details of a certification that satisfies the “condition of payment” element.¹⁵

Second, Simpson claims that she does not need to plead *scienter* to support her kickback allegations because her kickback allegations “are just one example and part of Bayer’s larger deceptive marketing scheme.” Opp. 30-31. Simpson is wrong again. Under the FCA, Simpson must at least allege that someone at Bayer knew that the claim was false. MTD 33; *see also supra* pp. 11, 14-15. Here, Simpson’s theory of liability is that certain claims for payment are false because healthcare providers falsely certified compliance with the Anti-Kickback Statute. SAC ¶ 208. But the Second Amended Complaint contains no allegation that anyone at Bayer knew that a claim was false for this reason. For example, she never alleges that anyone at Bayer (1) knew that a recipient of kickbacks would submit claims to the government, or (2) intended that the recipient of kickbacks would falsely certify compliance as a condition of payment and cause the

¹⁵ Simpson’s argument that no ““express certification”” is required, Opp. 30, is inapposite. Although some courts applying this theory have held that a fraudulent certification may be implied rather than express, the certification always must “be a condition of or prerequisite to government payment.” *Gross*, 415 F.3d at 604.

government actually to pay a false claim. Without such allegations, Simpson fails to state an Anti-Kickback-based FCA claim. Moreover, because Simpson has not alleged the necessary *scienter* for any FCA claim, *see supra* pp. 11, 14-15, these allegations also fail for the same reason that all of her other allegations fail.

Third, Simpson disputes Bayer's point that she fails to plead her kickback allegations with the particularity required by Rules 8(a) and 9(b) by claiming that "Bayer fails to cite a single authority supporting that any details need be provided concerning the healthcare providers' certification of compliance with the Anti-Kickback Statute." Opp. 31. Simpson is wrong here, as well. Bayer cited multiple cases in which "false certification" claims were dismissed because the complaint did not allege details showing that the provider receiving kickbacks actually submitted claims for government payment. *See* MTD 34-35 (citing *Barrett*, 251 F. Supp. 2d at 35 (D.D.C. 2003); *United States ex rel. Woods v. N. Ark. Reg'l Med. Ctr.*, 2006 WL 2583662, at *3-4 (W.D. Ark. Sept. 7, 2006)).

As a belated attempt to correct the deficiency of her allegations, Simpson attaches, as an exhibit to her opposition brief, a press release that her lawyer characterizes as demonstrating certain commitments Bayer agreed to make as part of an earlier settlement. *See* Sadowski Decl. ¶ 4 & Ex. 2. Simpson's last-ditch effort cannot cure the deficiencies in her complaint, *see supra* p. 9 (explaining the rule against considering evidence outside the complaint), but, in all events, the document is irrelevant to her claim. Simpson's theory of liability is that *healthcare providers* submitted false certifications, SAC ¶ 208, but all Simpson has provided is a press release purportedly describing commitments that Bayer agreed to make as part of a settlement. Nothing in the press release supports an

inference that any recipient of kickbacks actually submitted a claim to the Government, or that any healthcare provider made a certification that was a precondition of governmental payment. Indeed, the press release does not even support an inference that any undertaking *Bayer* agreed to make under the settlement agreement could be considered a precondition of governmental payment on claims submitted by healthcare providers.

For all these reasons, this Court should dismiss Simpson's repleaded anti-kickback allegations.

IV. SIMPSON'S STATE-LAW FCA CLAIMS MUST BE DISMISSED.

Bayer demonstrated that, in addition to her federal claims, Simpson's state law FCA claims should be dismissed. MTD 36-38. Each of the state laws at issue, like the federal law, requires fraud to be pled with particularity and has the same *scienter* requirement as the federal FCA. *Id.* at 37. Thus, the state law claims must be dismissed for the same failure to plead the claims with particularity or allege the necessary *scienter*. Moreover, many of the states have the same jurisdictional requirements as the federal FCA, requiring dismissal for the same reasons that the Court lacks jurisdiction over her federal FCA claims. *Id.* at 36-37. But, as Bayer showed, California, Hawaii, Nevada, and the District of Columbia have more stringent jurisdictional requirements, which Simpson fails to satisfy, and that Texas does not allow a private *qui tam* cause of action at all. *Id.* Similarly, although many of the state laws have statutes of limitations that mirror the federal FCA, California, Florida, and Louisiana have shorter limitation periods that bar far more of Simpson's claims, if not all of them. *Id.* at 37-38.

Simpson agrees generally that many of these state laws should be interpreted consistently with the federal FCA. Opp. 31. However, Simpson has no response to the fact that many of these state laws have more stringent jurisdictional requirements or statute of limitations periods. Because Simpson's FCA claims in her Second Amended Complaint fail to meet the requirements of Rule 9(b) and fail to allege the *scienter* necessary under the FCA, this Court should—as it did last time—dismiss her state law claims on these grounds. See Mem. Op. 34. Additionally, Simpson's claims under the laws of California, Florida, Hawaii, Louisiana, Nevada, Texas, and the District of Columbia should be dismissed with prejudice under the more stringent jurisdictional requirements or statute of limitations periods.

CONCLUSION

For the foregoing reasons and those stated in Bayer's opening memorandum, Simpson's Second Amended Complaint should be dismissed with prejudice in its entirety.

DATED: June 27, 2011

Respectfully submitted,

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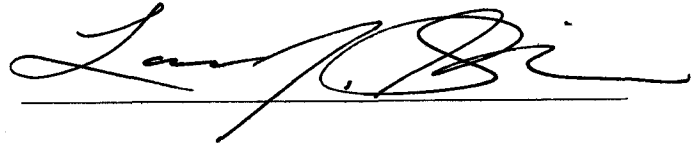
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CERTIFICATE OF SERVICE

I, Lowell J. Schiller, certify that true and correct copies of the foregoing Defendants' Reply in Support of Motion to Dismiss were electronically filed and served on June 27, 2011.

A handwritten signature in black ink, appearing to read "Lowell J. Schiller", is written over a horizontal line.